DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Minneapolis District
240 Hennepin Avenue
Minneapolis MN 55401-1999
Telephone: 612-334-4100

9 1873

October 19, 2001

WARNING LETTER

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Refer to MIN 02 – 04

Larry W. Linberg
Chief Executive Officer
Midwest Medical Holdings, LLC
dba Midwest Medical Services, Inc.
8400 Coral Sea Street NE
Blaine, Minnesota 55449

Dear Mr. Linberg:

During our inspection of your Midwest Medical Services, Inc. medical oxygen transfilling operation, on September 5, 6, and 10, 2001, located in Blaine, MN, our investigator found serious violations of the Current Good Manufacturing Practices (GMPs) for Finished Pharmaceuticals, Title 21, Code of Federal Regulations, Part 211 (21 CFR 211). Oxygen is a drug within the meaning of Section 201(g) of the Federal Food, Drug and Cosmetic Act (the Act). Your transfilled oxygen is adulterated within the meaning of Section 501(a)(2)(B) of the Act.

The violations observed during our inspection include but are not limited to the following:

1. Failure to adequately calibrate your ~~~~ oxygen analyzer used to test the purity and identity of Oxygen USP [21 CFR 211.160(b)(4)].

2. Failure to follow your written procedures to assure that correct labels are applied to your liquid Oxygen USP cryogenic vessels [21 CFR 21.130].

3. Failure to follow your written procedures in that there is no copy of the label for liquid oxygen USP [21 CFR 211.186].

The above indication of violations is not intended to be an all-inclusive list of deficiencies at your facility. It is your responsibility to ensure adherence to each requirement of the Good Manufacturing Practice Regulations. Federal agencies are

advised of the issuance of all Warning Letters about drugs so they may take this information into account when considering the award of contracts.

You should take prompt action to correct these deviations. Failure to promptly correct these deviations may result in regulatory action without further notice. Possible actions include seizure and/or injunction. This is official notification that FDA expects all your locations to be in compliance.

You should notify this office in writing, within 15 working days of receipt of this letter, of specific steps you have taken to correct the noted violations, including an explanation of each step being taken to prevent the recurrence of similar violations. If corrective action cannot be completed within 15 working days, state the reason for the delay and the time within which the corrections will be completed.

Your reply should be sent to Compliance Officer Carrie A. Hoffman at the address on the letterhead.

Sincerely,

James A. Rahto
Director
Minneapolis District

CAH/ccl